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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,302	12/22/2005	Maria Torpo	P05,0367	3792

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EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,302	TORPO ET AL.	
	Examiner	Art Unit	
	LUTHER G. BEHRINGER	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to application no. 10/562302 filed on 12/22/2005.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim(s) 27 – 33, 36 – 38, 41 – 43, 47 – 54, 57 – 59, 62 and 63 are provisionally rejected on the ground of nonstatutory double patenting over claim(s) 21, 22, 26 – 29, 31, 34, 35, 38 – 40 and 42 of copending Application No. 10/562109. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant

application are claiming common subject matter, as follows: Both inventions are directed toward pressure detection of diastolic heart failure.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim(s) 27 – 33, 36 – 38, 41 – 43, 47 – 54, 57 – 59, 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by **Baumann et al. (US 6,876,881, herein Baumann)**.

Baumann defines pulse pressure as the difference between peak systolic aortic pressure and end-diastolic aortic pressure. The examiner is interpreting a pressure measuring unit to comprise algorithms that operate on transient changes in atrial cycle length or ventricular cycle length to measure pulse pressure. Also, a pressure transducer may be disposed on a right or left ventricular pacing lead for determining

end-diastolic or end-systolic pressure as taught by Baumann. Baseline aortic pressure provides a reference value for a comparison with a comparator for determining an optimum paced site that provides a maximum increase in aortic pressure over the baseline aortic pressure. Baumann teaches hemodynamic performance is reflected in a patient's pulse pressure and that pacing can be used to improve the hemodynamics in congestive heart failure patients. Based on the hemodynamic performance obtained from the pressure comparisons, the diastolic heart failure state of the heart is determined.

With regard to **claim(s) 27 and 48,** Baumann discloses an implantable medical apparatus for detecting diastolic heart failure (DHF) comprising: a sensor adapted to interact with a heart to obtain information associated with functioning of the heart; and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration of a predetermined phase of diastole of the heart (Abstract).

Regarding **claim(s) 28 and 49,** Baumann discloses wherein said DHF determining device comprises a comparator, *microprocessor* **24**, capable of comparing said time duration with an upper limit value and a lower limit value to obtain a comparison result, said comparison result being indicative of said DHF state (Fig. 1).

With regard to **claim(s) 29 and 50,** Baumann inherently discloses wherein said DHF determining device comprises a calculating unit that calculates, from said information from said sensor, said time duration, as a time from an occurrence of peak

blood flow velocity through the mitral valve of the heart to a time of occurrence of zero blood flow velocity through the mitral valve of the heart (Abstract).

Regarding **claim(s) 30 and 51,** Baumann discloses wherein said calculating unit determines said time duration by extrapolating said mitral blood flow velocity to zero, if an actual occurrence of zero blood flow velocity through the mitral valve does not occur before an atrial contraction of the heart (Abstract).

With regard to **claim(s) 31 and 52,** Baumann inherently discloses wherein said calculating unit extrapolates the blood flow velocity to zero by determining a time derivative of blood flow velocity through the mitral valve shortly after said occurrence of said peak blood flow velocity through the mitral valve (Abstract).

Regarding **claim(s) 32 and 53,** Baumann inherently discloses wherein said sensor senses an IEGM signal from the heart, and wherein said calculating unit calculates the time of occurrence of said peak blood flow velocity through the mitral valve to the time of occurrence of zero blood flow velocity through the mitral valve from said IEGM (Col. 6, Lines 30 – 35).

With regard to **claim(s) 33 and 54,** Baumann discloses wherein said sensor is an impedance sensor that senses an impedance of the heart, and wherein said calculating unit calculates the time from the occurrence of said peak blood flow velocity through the mitral valve to zero blood flow velocity through the mitral valve from said impedance (Col. 2, Lines 42 – 45).

Regarding **claim(s) 36 and 57,** Baumann discloses wherein said DHF determining device comprises a calculating unit that calculates, as said time duration, and isovolumic relaxation time (IVRT) from said information from said sensor (Abstract).

With regard to **claim(s) 37 and 58,** Baumann inherently discloses wherein said sensor detects an IEGM from the heart, and wherein said calculating unit determines said IVRT from said IEGM (Col. 6, Lines 30 – 35).

Regarding **claim(s) 38 and 59,** Baumann discloses wherein said sensor is an impedance sensor that measures an impedance of the heart, and wherein said calculating unit calculates said IVRT from said impedance (Col. 2, Lines 42 – 45).

With regard to **claim(s) 41 and 62,** Baumann discloses wherein said DHF determining device determines said time duration, *delays*, respectively at predetermined time intervals, thereby obtaining a plurality of time durations, and comprises a memory in which said plurality of time durations are stored (Abstract, Fig. 2).

Regarding **claim 42,** Baumann inherently discloses wherein said DHF determining device determines said time duration respectively at a plurality of predetermined time intervals, *delays*, and comprises a comparator, *microprocessor* **24**, capable of comparing each of said time durations to an upper limit value to identify a first plurality of time durations above said upper limit value and respective first magnitudes of respective deviations of said first plurality of time durations from said upper limit value, and a second plurality of time durations below said lower limit value and second magnitudes of deviations of said second plurality of time durations from

said lower limit value, and comprises a memory in which said first plurality of time durations, said first magnitudes, said second plurality of time durations, and said second magnitudes are stored (Fig. 1, 2; Abstract).

With regard to **claim(s) 43 and 63,** Baumann inherently discloses wherein said DHF determining device determines said time duration at a plurality of different times, and determines changes in the respective time durations determined at said different times, and comprises a memory in which said changes are stored, *adjust AV delay and interventricular delay to achieve optimum hemodynamic performance* (Abstract).

Regarding **claim 46,** Baumann wherein said DHF determining device determines said time duration at respectively different times and detects a change in said time duration detected at respectively different times, and comprises a comparator that compares said change to a predetermined threshold value, and an alerting unit that emits a humanly perceptible alert if said change exceeds said predetermined threshold value, *adjust AV delay and interventricular delay to achieve optimum hemodynamic performance* (Abstract).

With regard to **claim 47,** Baumann discloses an implantable cardiac pacemaker comprising: a pulse generator, **26**, that emits stimulation pulses; an electrode system, **14**, adapted to interact with the heart of a subject to deliver said stimulation pulses to the heart in a pacing therapy regimen, a sensor adapted to interact with a heart to obtain information associated with functioning of the heart, **18 and 22**, and a DHF determining device supplied with said information that detects a DHF state of the heart

from said information by determining, as a DHF parameter, a time duration, *delay*, of a predetermined phase of diastole of the heart; and a control unit, *microprocessor* ***24***, connected to said DHF determining device and to said pulse generator, said control device controlling said pulse generator to modify said pacing therapy regimen dependent on said DHF parameter (Abstract, Fig. 1).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim(s) 34, 35, 39, 40, 55, 56, 60 and 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Baumann et al. (US 6,876,881, herein Baumann)** in view of **Salo et al (US 5,334,222, herein Salo)**.

Baumann fails to disclose the use of an accelerometer to detect an activity signal of a patient.

Salo teaches the use of an accelerometer to detect an activity signal of a patient (Col. 2, Lines 55 – 59).

9. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of using an accelerometer to detect an activity signal of a patient. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Baumann to include an accelerometer as taught by Salo, since accelerometers provide a compact efficient means by which activity signals may be monitored.

10. Claim(s) 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Baumann et al. (US 6,876,881, herein Baumann)** in view of **Paul et al. (US 5,814,088, herein Paul)**.

Baumann fails to disclose an alerting unit that emits a humanly perceptible alert.

However, Paul discloses an alerting unit that emits a humanly perceptible alert (Col. 2, Lines 13 – 32).

11. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of utilizing an alerting unit to achieve notification of a patient of an alert situation. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Baumann to include an alerting unit as taught by Paul, since notifying a patient of a problem can aid in the correction of that issue and potentially improve the patient's quality of life.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766